The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 8, 2006.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E6–9269 Filed 6–13–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: HIV Prevention Projects for Young Men of Color Who Have Sex With Men and Young Transgender Persons of Color, Funding Opportunity Announcement (FOA) PS06–618

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: HIV Prevention Projects for Young Men of Color Who Have Sex With Men and Young Transgender Persons of Color, FOA PS06–618.

Times and Dates:

9 a.m.–12 p.m., June 26, 2006 (Closed).
9 a.m.–5 p.m., June 27, 2006 (Closed).
9 a.m.–5 p.m., June 28, 2006 (Closed).
9 a.m.–5 p.m., June 29, 2006 (Closed).
9 a.m.–5 p.m., June 30, 2006 (Closed).

Place: W Hotel Atlanta at Perimeter Center, 111 Perimeter Center West, Atlanta, Georgia 30346, Telephone 770.396.6800.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to "HIV Prevention Projects for Young Men of Color Who Have Sex With Men and Young Transgender Persons of Color," FOA PS06–618.

For Further Information Contact: Beth Wolfe, Resource Funding Analyst, Funding Activities Services Office, Extramural Funding Activities Unit, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS E–07, Atlanta, GA 30333, Telephone 404.639.8531.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 8, 2006.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E6–9270 Filed 6–13–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following Federal Committee meeting.

Correction: This notice was published in the **Federal Register** on June 9, 2006, volume 71, number 111, pages 33456–33457. "Additional Information" that was published on April 3, 2006, volume 71, number 63, page 16582, and a change to the 'status' has been added.

Name: Advisory Committee on Immunization Practices (ACIP).

Times and Dates:

8 a.m.–6 p.m., June 29, 2006.
8 a.m.–4 p.m., June 30, 2006.

Place: Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Building 19 (Global Communications Center), Room 232, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available. Meeting space accommodates approximately 330 people. Overflow space for real-time viewing will be available.

Additional Information: In order to expedite the security clearance process at the CDC Clifton Road Campus, all ACIP attendees are now required to register online at *http://www.cdc.gov/nip/acip*, which can be found under the "Upcoming Meetings" tab. Please be sure to complete all the required fields before submitting your registration and submit no later than June 22, 2006.

Please Note: All non-U.S. Citizens must pre-register by June 18, 2006 or they will not be allowed access to the campus and will *not* be allowed to register on site. All non-U.S. Citizens are required to complete the "Access Request Form" and register online at *http://www.cdc.gov/nip/acip*. The access request form can be obtained by contacting Demetria Gardner at 1–404–639–8836 and should be e-mailed upon completion directly to Ms. Gardner at *dgardner@cdc.gov*.

For Further Information Contact: Demetria Gardner, Immunization Services Division, National Center for Immunization and Respiratory Diseases (proposed), CDC, 1600 Clifton Road, NE., (E–05), Atlanta, Georgia 30333, telephone 404/639–8836, fax 404/639–8905.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 8, 2006.

B. Kathy Skipper,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E6–9266 Filed 6–13–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002E–0100]

Determination of Regulatory Review Period for Purposes of Patent Extension; DUTASTERIDE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DUTASTERIDE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–

417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product DUTASTERIDE (dutasteride). DUTASTERIDE is indicated for the treatment of symptomatic benign prostatic hyperplasia in men with an enlarged prostate gland. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for DUTASTERIDE (U.S. Patent No. 5,565,467) from GlaxoSmithKline, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 31, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of DUTASTERIDE represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for DUTASTERIDE is 2,373 days. Of this time, 2,038 days occurred during the testing phase of the regulatory review period, while 335 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: May 25, 1995. The applicant claims April 24, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 25, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 21, 2000. FDA has verified the applicant's claim that the new drug application (NDA) for DUTASTERIDE (NDA 21–319) was initially submitted on December 21, 2000.

3. *The date the application was approved*: November 20, 2001. FDA has verified the applicant's claim that NDA 21–319 was approved on November 20, 2001.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 769 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by August 14, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 11, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–9224 Filed 6–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0042]

Determination of Regulatory Review Period for Purposes of Patent Extension; CUBICIN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CUBICIN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes